



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket No. FDA-2014-M-0799]

Medical Devices; Neurological Devices; Classification of the Transcutaneous Electrical Nerve Stimulator to Treat Headache

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the transcutaneous electrical nerve stimulator to treat headache into class II (special controls). The special controls that will apply to the device are identified in this order, and will be part of the codified language for the transcutaneous electrical nerve stimulator to treat headache classification. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The classification was applicable on March 11, 2014.

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## SUPPLEMENTARY INFORMATION:

### I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Public Law 112-144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1). Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, the person requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a

classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of “low-moderate risk” or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA will classify the device by written order within 120 days. This classification will be the initial classification of the device.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on November 20, 2012, classifying the Cefaly Device, into class III, because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device which was subsequently reclassified into class I or class II. On December 13, 2012, STX-Med SPRL, submitted a request for classification of the Cefaly Device under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act. FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the de novo request, FDA determined that the device can be classified into class II with the

establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on March 11, 2014, FDA issued an order to the requester classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 882.5891.

Following the effective date of this final classification administrative order, any firm submitting a premarket notification (510(k)) for a transcutaneous electrical nerve stimulator to treat headache will need to comply with the special controls named in the final administrative order.

The device is assigned the generic name transcutaneous electrical nerve stimulator to treat headache, and it is identified as a device used to apply an electrical current to a patient's cranium through electrodes placed on the skin.

FDA has identified the following risks to health associated with this type of device and the measures required to mitigate these risks in table 1:

Table 1.--Transcutaneous Electrical Nerve Stimulator to Treat Headache Risks and Mitigation Measures

Identified Risks	Mitigation Measures
Adverse reactions to skin-contacting materials	Biocompatibility testing Labeling
Electrical, mechanical, or thermal hazards that may result in user discomfort or injury	Electromagnetic compatibility testing Electrical, mechanical, and thermal safety testing Technical parameters Electrode performance testing Software verification, validation, and hazard analysis Labeling
Ineffective treatment	Clinical performance data Labeling
Failure to identify the correct population	Clinical performance data Labeling
Misuse that may result in user discomfort, injury, or delay treatment for headaches	Labeling

FDA believes that the following special controls, in addition to the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness:

- The patient-contacting components of the device must be demonstrated to be biocompatible.
- Appropriate analysis/testing must validate electromagnetic compatibility and electrical, mechanical, and thermal safety.
- The technical parameters of the device, including waveform, output modes, maximum output voltage and current (with 500, 2,000, and 10,000 ohm loads), pulse duration, frequency, net charge ( $\mu\text{C}$ ) per pulse, maximum phase charge at 500 ohms, maximum current density ( $\text{mA}/\text{cm}^2$ , r.m.s.), maximum average current (mA), maximum average power density ( $\text{W}/\text{cm}^2$ ), and the type of impedance monitoring system must be fully characterized.
- Electrical performance, adhesive integrity, shelf life, reusability, and current distribution testing of the electrodes must be conducted.
- Appropriate software verification, validation, and hazard analysis must be performed.
- Clinical performance data must demonstrate that the device is safe and effective as a treatment for headache in the indicated patient population.
- Labeling must include the following:
  - Appropriate contraindications such as not for use in subjects with an implanted metallic or electronic device in the head, a cardiac pacemaker, or an implanted or wearable defibrillator;
  - appropriate warnings such as not to apply the device on the neck or chest, not to use the device in the presence of electronic monitoring equipment, not to use in the bath or shower, not to use while sleeping, not to use while driving, not to use while operating machinery;

- appropriate precautions such as the long-term effects of chronic use of the device are unknown;
- a summary of the expected risks and benefits of using the device;
- a summary of the clinical performance data, including information on the patient population for which the device has and has not been demonstrated to be effective, and any adverse events and complications;
- information on how the device operates and the typical sensations experienced during treatment;
- a detailed summary of the device technical parameters;
- an expiration date/shelf life for the electrodes and the number of times they can be reused; and
- disposal instructions.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification prior to marketing the device, which contains information about the transcutaneous electrical nerve stimulator to treat headache device they intend to market.

## II. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

## III. Paperwork Reduction Act of 1995

This final administrative order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910-0120, and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910-0485.

## IV. Reference

The following reference has been placed on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at <http://www.regulations.gov>.

1. K122566 De Novo Petition for the Cefaly Device From STX-Med SPRL, dated December 13, 2012.

List of Subjects in 21 CFR Part 882

Medical devices, Neurological devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 882 is amended as follows:

PART 882--NEUROLOGICAL DEVICES

1. The authority citation for 21 CFR part 882 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Add § 882.5891 to subpart F to read as follows:

§ 882.5891 Transcutaneous electrical nerve stimulator to treat headache.

(a) Identification. A transcutaneous electrical nerve stimulator to treat headache is a device used to apply an electrical current to a patient's cranium through electrodes placed on the skin.

(b) Classification. Class II (special controls). The special controls for this device are:

- (1) The patient-contacting components of the device must be demonstrated to be biocompatible.
- (2) Appropriate analysis/testing must validate electromagnetic compatibility and electrical, mechanical, and thermal safety.
- (3) The technical parameters of the device, including waveform, output modes, maximum output voltage and current (with 500, 2,000, and 10,000 ohm loads), pulse duration, frequency, net charge ( $\mu\text{C}$ ) per pulse, maximum phase charge at 500 ohms, maximum current density ( $\text{mA}/\text{cm}^2$ , r.m.s.), maximum average current (mA), maximum average power density ( $\text{W}/\text{cm}^2$ ), and the type of impedance monitoring system must be fully characterized.
- (4) Electrical performance, adhesive integrity, shelf life, reusability, and current distribution testing of the electrodes must be conducted.
- (5) Appropriate software verification, validation, and hazard analysis must be performed.



(6) Clinical performance data must demonstrate that the device is safe and effective as a treatment for headache in the indicated patient population.

(7) Labeling must include the following:

(i) Appropriate contraindications such as not for use in subjects with an implanted metallic or electronic device in the head, a cardiac pacemaker, or an implanted or wearable defibrillator.

(ii) Appropriate warnings such as not to apply the device on the neck or chest, not to use the device in the presence of electronic monitoring equipment, not to use in the bath or shower, not to use while sleeping, not to use while driving, not to use while operating machinery.

(iii) Appropriate precautions such as the long-term effects of chronic use of the device are unknown.

(iv) A summary of the expected risks and benefits of using the device.

(v) A summary of the clinical performance data, including information on the patient population for which the device has and has not been demonstrated to be effective, and any adverse events and complications.

(vi) Information on how the device operates and the typical sensations experienced during treatment.

(vii) A detailed summary of the device technical parameters.

(viii) An expiration date/shelf life for the electrodes and the number of times they can be reused.

(ix) Disposal instructions.

Dated: June 27, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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